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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,371	08/27/2001	Gust H. Bardy	032580.0004.CIP1	5209

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CROMPTON SEAGER AND TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER
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MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/940,371

Applicant(s)

BARDY ET AL. 

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The indicated allowability of claims 1-2, 5-8, 10-19, 22-31, 34-37, 39-43,45-47,50-53,55-58, 61-73, 87-8993-97, 125, 153, and 164 are withdrawn in view of the newly discovered reference(s) to Volz (5,755,743). Rejections based on the newly cited reference(s) follow.

#### ***Claim Objections***

2. Claim 26 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 26 is dependent on claim 26.

#### ***Claim Rejections - 35 USC § 112***

3. Claims 93-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 93-95 recite the limitation "the curved portion of the second segment" in lines 1-

2. There is insufficient antecedent basis for this limitation in the claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2, 5, 8, 10-12, 15, 18-19, 22, 25, 28-29, 34, 37, 39-40, 46-47, 50, 53, 55, 58, 61, 65, 68, 71, 87-89, 93, 96-97, 125, 153, and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743).

Regarding claims 1, 28, 46, and 164, Volz shows a housing having a curved portion (bottom) comprising a first segment (top portion) and a second segment (bottom portion), each segment having an insulating plate (26, 16) at an end thereof, and a conductive plate (18, top plate of 10) coupled to the insulating plate (26, 16), wherein the conductive plate of the first segment is coupled to the conductive plate of the second segment, and cardioversion defibrillation circuitry or an electrical circuit (11) located within the housing (Fig. 1).

Although Volz fails to show an electrically conductive surface or electrode disposed on the housing, it is well known in the art to provide an electrode on the housing. See for example: Adams (5,601,607), Adams et al. (5,531,764), Bardy (5,292,338) & (5,314,430), Hauser et al. (5,385,574), and Kroll (5,522,853). Therefore, it would have been obvious at the time the invention was made to modify the device of Volz to include an electrode disposed on the housing since it is well known in the art to do so.

Assuming arguendo that Volz fails to show a conductive plate for one of bottom segment, it is well known to form the pacemaker housing with a top plate. See for example: Boer

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(4,010,759) (Fig. 4), Comben (4,057,068) (Fig. 1), and Hassler et al. (5,470,345) (Fig. 1) & (5,782,891) (Fig. 2). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form the bottom segment of the Volz device with a conductive plate.

Regarding claims 2, and 47, Volz shows the housing comprises an electrically insulated material (16, 26).

With respect to claims 5, 34 and 50, Volz shows the housing comprises a ceramic material (24).

Regarding claims 8, 37, and 53, Volz shows the housing comprises a mixture of ceramic materials (24) and metal (10). Although Volz fails to specifically teach the metal is titanium, it is well known in the art to utilize titanium in a housing. See for example: Boer (4,010,759) Comben (4,057,068) Hassler et al. (5,470,345) (Fig. 1) & (5,782,891), and Hauser (5,385,574). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a housing comprising titanium in place of metal since utilization of titanium in housings is well known.

With respect to claim 10, Volz shows at least a portion of the first segment is curved (18) (Fig. 1)

Regarding claim 11, Volz shows at least a portion of the second segment is curved (10) (Fig. 1).

With respect to claims 12, and 39-40, shows the curved portion (bottom) of the housing comprises a circular arc approximately 1 radians to approximately 180 radians in length.

Regarding claim 15, Volz shows the curved portion of the second segment comprises a circular arc (Fig. 1).

With respect to claim 18, Volz shows the second segment of the housing is substantially straight (Fig.1).

Regarding claim 19, Volz shows the first segment of the housing is contiguous with the second segment of the housing (Fig. 1)

With respect to claims 22, 25, 29, 68, and 71, Volz shows the electrical circuit can provide cardioversion defibrillation and emits an energy for shocking the patient's heart (Col. 1, lines 17-18).

Regarding claim 46, Volz further shows the housing has a top surface and a bottom surface, wherein at least a portion of the bottom surface (10) of the housing is non-planar (bottom) (Fig. 1).

With respect to claim 55, Volz shows the portion of the bottom surface of the housing being non-planar comprise a circular arc.

Regarding claim 58, Volz shows the bottom surface of the housing is substantially smooth.

With respect to claim 61, Volz shows a portion of the top surface (18) of the housing is substantially non-planar (top) (Fig. 1)

Regarding claim 65, Volz shows the top surface of the housing is substantially smooth.

With respect to claim 87, Volz shows the housing comprises a mixture of conductive (10, 18) and nonconductive materials (16, 26) and a portion of the housing is curved

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Regarding claim 88, Volz shows at least a portion of the first segment is curved (18) (Fig.

1)

With respect to claim 89, Volz shows at least a portion of the second segment is curved (18) (Fig. 1).

Regarding claim 93, Volz shows the curved portion of the second segment comprises a circular arc (Fig. 1).

With respect to claim 96, Volz shows the second segment of the housing is substantially straight (Fig.1).

Regarding claim 97, Volz shows the first segment of the housing is contiguous with the second segment of the housing (Fig. 1)

With respect to claims 125, and 153, Volz further shows the housing comprises a mixture of conductive (10, 18) and nonconductive materials (16, 26).

6. Claims 1-2, 5, 8, 10-12, 15, 18-19, 22, 25-31, 34, 37, 39-40, 43, 45-47, 50, 53, 55, 58, 61-62, 65-68, 71-73, 87-89, 93, 96-97, 125, 153, and 164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743) in view of Hauser (5,385,574).

Regarding claims 1, 28, 46, and 164, Volz shows a housing having a curved portion (bottom) comprising a first segment (top portion) and a second segment (bottom portion), each segment having an insulating plate (26, 16) at an end thereof, and a conductive plate (18, top plate of 10) coupled to the insulating plate (26, 16), wherein the conductive plate of the first segment is coupled to the conductive plate of the second segment, and cardioversion defibrillation circuitry or an electrical circuit (11) located within the housing (Fig. 1).

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Assuming *arguendo* that Volz fails to show a conductive plate for one of bottom segment, it is well known to form the pacemaker housing with a top plate. See for example: Boer (4,010,759) (Fig. 4), Comben (4,057,068) (Fig. 1), and Hassler et al. (5,470,345) (Fig. 1) & (5,782,891) (Fig. 2). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to form the bottom segment of the Volz device with a conductive plate.

Although Volz fails to show an electrically conductive surface or electrode disposed on the housing, attention is directed to Hauser et al. which shows an electrode disposed on the housing. Hauser et al. teaches the electrode disposed on the housing is useful for defibrillating the heart. Therefore, it would have been obvious at the time the invention was made to modify the device of Volz to include an electrode disposed on the housing as Hauser et al teaches since it is since it is useful for defibrillating the heart.

Regarding claims 2 and 47, Hauser et al. shows the housing comprises at least one electrically insulated surface (82).

Regarding claims 2, and 47, Volz shows the housing comprises an electrically insulated material (16, 26).

With respect to claims 5, 34, and 50, Volz shows the housing comprises a ceramic material (24).

With respect to claims 5, 8, 34, 37, 50, and 53, Hauser et al. shows the housing comprises a mixture of ceramic and titanium (Col. 6, lines 49-60).

With respect to claims 10-11, Volz shows at least a portion of the first segment is curved (18) and at least a portion of the second segment is curved (10) (Fig. 1).



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With respect to claims 12, and 39-40, Volz shows the curved portion of the housing comprises a circular arc approximately 1 radians to approximately 180 radians in length (Fig. 1).

Regarding claims 12, 39-40, 55, and 62, Hauser et al. shows the curved portion (the edges) of the housing comprises a circular arc approximately 1 radians to 180 radians in length (Fig. 11).

With respect to claim 18, Volz shows the second segment of the housing is substantially straight (Fig. 1).

Regarding claim 19, Volz shows the first segment of the housing is contiguous with the second segment of the housing (Fig. 1).

With respect to claim 18, Hauser et al. shows the second segment of the housing is substantially straight (Figs. 8, 11).

Regarding claim 19, Hauser et al. shows the first segment of the housing is contiguous with the second segment of the housing (Figs. 8, 11).

With respect to claims 22, 25, 29, 68, and 71, Volz shows the electrical circuit can provide cardioversion defibrillation and emits an energy for shocking the patient's heart (Col. 1, lines 17-18).

With respect to claims 22, 25, 29, 68, and 71, Hauser et al. shows the electrical circuit can provide cardioversion defibrillation (Abs) and the electrically conductive surface (electrode) (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Col. 2, lines 29-34).

Regarding claims 26-27, 30-31, and 72-73, Hauser et al. shows the electrically conductive surface can receive sensory information (Col. 7, lines 9-15).

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With respect to claim 28, Hauser et al shows the at least one electrode (62, 64) is integrally disposed in the at least one curved portion of the housing such that the at least one electrode is maintained in a predetermined relationship subcutaneously over the patient's ribs and cardioversion defibrillation circuitry located within the housing and coupled to the at least one electrode (Figs. 8, 11).

Regarding claim 43, Hauser et al. shows the predetermined relationship is with respect to the patient's heart.

With respect to claim 45, Hauser et al. shows the circuitry provides waveform cardiac pacing for a patient's heart (Col. 5, lines 27-32).

Regarding claim 46, Hauser et al. shows a housing having a top surface and a bottom surface, wherein at least a portion of the bottom surface is non-planar (the edges) and wherein the electrode can provide an effective electric field for myocardial cardioversion and defibrillation (Col. 2, lines 29-34).

Regarding claim 46, Volz further shows the housing has a top surface and a bottom surface, wherein at least a portion of the bottom surface (10) of the housing is non-planar (bottom) (Fig. 1).

With respect to claim 55, Volz shows the portion of the bottom surface of the housing being non-planar comprise a circular arc.

With respect to claims 58, and 65, Hauser et al. shows the bottom surface and top surface of the housing are substantially smooth (Fig. 11).

Regarding claim 61, Hauser et al. shows a portion of the top surface of the housing is substantially non-planar (the edges) (Fig. 11).

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With respect to claim 61, Volz shows a portion of the top surface (18) of the housing is substantially non-planar (top) (Fig. 1).

Regarding claim 65, Volz shows the top surface of the housing is substantially smooth.

With respect to claim 66, Hauser et al. shows the bottom surface (surface that faces the heart) further comprises a proximal end and a distal end, wherein an electrode (62) is integrally positioned at the proximal end (left) of the bottom surface (Fig. 11).

Regarding claim 67, Hauser et al shows a second electrode (64) is integrally positioned at the distal end (right) of the bottom surface (Fig. 11).

With respect to claim 87, Volz shows the housing comprises a mixture of conductive (10, 18) and nonconductive materials (16, 26) and a portion of the housing is curved

Regarding claim 88, Volz shows at least a portion of the first segment is curved (18) (Fig. 1).

With respect to claim 89, Volz shows at least a portion of the second segment is curved (18) (Fig. 1).

Regarding claim 93, Volz shows the curved portion of the second segment comprises a circular arc (Fig. 1).

With respect to claim 96, Volz shows the second segment of the housing is substantially straight (Fig. 1).

Regarding claim 97, Volz shows the first segment of the housing is contiguous with the second segment of the housing (Fig. 1).

With respect to claims 125, and 153, Volz further shows the housing comprises a mixture of conductive (10, 18) and nonconductive materials (16, 26).

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7. Claims 6-7, 35-36, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743) as applied to claims 5, 34, and 50, above and further in view of Mech et al. (2002/0120296). Volz discloses the claimed invention except for specifically showing the type of ceramic used. Mech et al. teaches that implantable medical devices are typically made of ceramics including zirconia, stabilized zirconia, partially stabilized zirconia, tetragonal zirconia, magnesia stabilized zirconia, ceria stabilized zirconia, yttria stabilized zirconia, and calcia stabilized zirconia (Para. 0003). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize zirconia, partially stabilized zirconia or stabilized zirconia for the ceramic of Volz since it is typically used for constructing implantable medical devices.

8. Claims 6-7, 35-36, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743) in view of Hauser et al. (5,385,574) as applied to claims 5, 34, and 50, above and further in view of Mech et al. (2002/0120296). Volz discloses the claimed invention except for specifically showing the type of ceramic used. Mech et al. teaches that implantable medical devices are typically made of ceramics including zirconia, stabilized zirconia, partially stabilized zirconia, tetragonal zirconia, magnesia stabilized zirconia, ceria stabilized zirconia, yttria stabilized zirconia, and calcia stabilized zirconia (Para. 0003). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize zirconia, partially stabilized zirconia or stabilized zirconia for the ceramic of Volz since it is typically used for constructing implantable medical devices.

9. Claims 13-14, 15-17, 41-42, 56-57, 62-64, and 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743). Volz discloses the claimed invention except for

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the curved portion, the curved portion of the first segment, the curved portion of the second segment, the non-planar bottom surface, or the non-planar top surface comprising an elliptical curve or a nonsymmetrical arc. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the curved portion, non-planar bottom surface, or non-planar top surface as taught by Volz. with an elliptical curve or nonsymmetric arc, since applicant has not disclosed that these particular types of curves provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any curve such as the curve taught by Volz for forming the edge of the curved portion, the curved portion of the first segment, the curved portion of the second segment, the non-planar bottom surface, or the non-planar top surface.

10. Claims 13-14, 15-17, 41-42, 56-57, 62-64, and 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743) in view of Hauser et al. (5,385,574). Volz and Hauser et al. disclose the claimed invention except for the curved portion, the curved portion of the first segment, the curved portion of the second segment, the non-planar bottom surface, or the non-planar top surface comprising an elliptical curve or a nonsymmetrical arc. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the curved portion, non-planar bottom surface, or non-planar top surface as taught by Volz and Hauser et al. with an elliptical curve or nonsymmetric arc, since applicant has not disclosed that these particular types of curves provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any curve such as the curve taught by Volz and Hauser et al. for forming the edge of the curved portion, the curved

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portion of the first segment, the curved portion of the second segment, the non-planar bottom surface, or the non-planar top surface.

11. Claims 23-24, 45, and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743) as applied to claims 1, 22, 28, 46, and 68, above and further in view of Mower (5,871,506). Volz discloses the claimed invention except for setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic pacing pulses as Mower teaches with the device of Volz. since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

12. Claims 23-24, 45, and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (5,755,743) in view of Hauser et al. (5,385,574). as applied to claims 1, 22, 28, 46, and 68, above and further in view of Mower (5,871,506). Volz and Hauser et al. disclose the claimed invention except for setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic pacing pulses as Mower teaches with the device of Volz and Hauser et al. since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

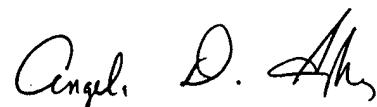
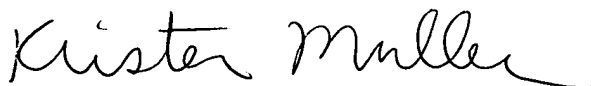
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kdm



ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

Continuation of Disposition of Claims: Claims pending in the application are 1,2,5-8,10-19,22-31,34-37,39-43,45-47,50-53,55-58,61-73,87-89,93-97,125,153 and 164.

Continuation of Disposition of Claims: Claims rejected are 1,2,5-8,10-19,22-31,34-37,39-43,45-47,50-53,55-58,61-73,87-89,93-97,125,153 and 164.